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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,245	11/12/2003	Duane D. Blatter	11502/33	6387

32642 7590 07/26/2006

STOEL RIVES LLP - SLC  
201 SOUTH MAIN STREET  
ONE UTAH CENTER  
SALT LAKE CITY, UT 84111

EXAMINER
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WOO, JULIAN W

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/706,245

Applicant(s)

BLATTER, DUANE D.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-100 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 53-68, 85-100 is/are allowed.
- 6) ☒ Claim(s) 21-26, 28-34, 37-42, 44-50, 69-73, 76-82 is/are rejected.
- 7) ☒ Claim(s) 27, 35, 36, 43, 51, 52, 74, 75, 83, 84 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/19/04, 3/27/06</u> .   | 6) <input type="checkbox"/> Other: _____                                    |

3. continued. 5/30/06, 7/13/06

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 26 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In each of these claims, "the extravascular device" lacks antecedent basis.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 21-25, 28-34, 37-41, 44-50, 69-73, and 76-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilk (5,330,486). Wilk discloses the invention substantially as claimed. Wilk discloses, at least in figures 13 and 18B-18D and in col.

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15, line 46 to col. 16, line 8 and col. 17, line 44 to col. 18, line 59, a method for anastomosis of an open end of a graft vessel (e.g., TOS 4 as seen in fig. 13) to a side of a receiving vessel (e.g., TOS3 as seen in fig. 13), where the method includes positioning an anvil (370 as seen in figures 18B-18D) within a lumen of the receiving vessel, manipulating the anvil via a component (388) extending from the anvil to cause a region of the receiving vessel inherently to stretch and to conform to the shape of the a portion of the anvil contacting the wall of the receiving vessel without the anvil passing through the wall of the receiving vessel, joining the graft vessel to the side of the receiving vessel, forming an anastomosis opening in the wall of the receiving vessel at the anastomosis site (via 388), where the opening is formed before the graft vessel and the receiving vessel are joined together, where forming the opening occurs simultaneously with joining the graft vessel to the side of the receiving vessel, where a portion of the anvil contacting the region of wall of the receiving vessel is convex (i.e., the side of the anvil is circular or rounded), where the component extending from the anvil is a piercing wire (388) or positioning stem, where joining the graft vessel to the side of the receiving vessel at the anastomosis site is achieved by driving a circular array of diametrically opposed staples through the vessels and against the anvil, where a portion of the wall of the receiving wall of the receiving vessel between the anvil and a component of an extravascular device (384), and where the anvil is removed via an opening used to achieve introduction of the anvil into the lumen of the receiving vessel (e.g., NT3 as seen in fig. 13). However, Wilk does not specifically disclose forming an anastomosis opening in the wall of the receiving vessel after the graft vessel and the

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receiving vessel are joined together (as shown in fig. 18D). Nevertheless, Wilk discloses, at least in col. 15, lines 46-51, an anvil member (244) and stapling member (246) analogous to the abovementioned anvil (370) and extravascular device (384), where anvil member and the stapling member are used for "cutting of an [anastomosis] opening inside an endless staple array" in the wall of a receiving vessel after a graft vessel and a receiving vessel are joined together. It would have been obvious to one having ordinary skill in the art at the time the invention was made, to form an anastomosis opening in the wall of the receiving vessel after the graft vessel and the receiving vessel are joined together. Such an opening would achieve the desired communication between the lumens of hollow organ segments connected together in an anastomosis.

***Allowable Subject Matter***

5. Claims 53-68 and 85-100 are allowed.
6. The following is an examiner's statement of reasons for allowance: None of the prior art of record, alone or in combination, discloses a method for anastomosis of a graft vessel to a side of a receiving vessel, where the method includes, inter alia, positioning an anvil within a lumen of a receiving vessel, joining a graft vessel to the side of the receiving vessel, forming an anastomosis opening in the side of the receiving vessel, and removing the anvil from the anastomosis site after joining of the vessel and formation of the anastomosis opening, where prior to joining the vessels, a portion of the wall of the receiving vessel is held between the anvil and a component of an extravascular device, such that a region of the wall conforms to the shape of a portion of

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the anvil contacting the region and such that at least part of the region extends beyond the portion of the wall held between the anvil and the component of the extravascular device or extends into the lumen of the graft vessel, where the extravascular device is positioned outside of the graft vessel lumen.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

7. Claims 27, 35, 36, 43, 51, 52, 74, 75, 83, and 84 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a method for anastomosis of an open end of a graft vessel to a side of a receiving vessel, where the method includes, inter alia, positioning an anvil within a lumen of the receiving vessel, manipulating the anvil via a component extending from the anvil to cause a region of the receiving vessel to stretch and to conform to the shape of the a portion of the anvil contacting the wall of the receiving vessel, joining the graft vessel to the side of the receiving vessel, and forming an anastomosis opening in the wall of the receiving vessel at the anastomosis site, where prior to joining the graft vessel to the side of the receiving vessel, the region of the wall of the receiving vessel is caused to stretch and

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to conform to the shape of the portion of the anvil is drawn into the lumen of the graft vessel; or where prior to forming an anastomosis opening, the stretched region of the receiving vessel is extended into an opening of the component of an extravascular device; where the receiving vessel is a blood vessel, and where the receiving vessel is pressurized as the graft vessel and receiving vessel are anastomosed.

### ***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Nicolo (6,520,398) teach methods for anastomosis of hollow organs.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should



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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Julian W. Woo". The signature is fluid and cursive, with the first name "Julian" being more prominent than the last name "Woo".

Julian W. Woo  
Primary Examiner

July 21, 2006